September 8, 1999

Jane Henney, M.D., Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, MD 20857

5378 '99 SEP 23 P2:07

Subject: Labeling Criteria for Nutritional Supplements

Dear Commissioner Henney:

My wife and I have been taking nutritional supplements for over twenty years. Our initial decision to make vitamin C and E supplements a regular part of our diet was based on our review of studies conducted by credentialed medical / scientific authorities. Since that time, we have added additional supplements to our diet.

Over the years, my wife has continued to read extensively in the areas of diet and nutritional supplements. In this regard, we regularly read publications by medical doctors who have an active interest in diet and nutrition. We consider ourselves to be better informed about dietary issues than most Americans only because of our self-directed efforts. This is the main reason for my letter.

Based on our readings, my wife and I can only conclude that ordinary people in this country are woefully ignorant of the "dietary facts of life". Witness the proliferation of processed, hydrogenated foods in the high-fat diet so many Americans consume. Without even getting deep into the technical specifics, I think its fair to say that competent scientific authorities agree that certain nutritional supplements would be of benefit to most Americans.

Unfortunately, the medical community – including the FDA – has not been proactive in this area. Bluntly put, we have long considered the FDA position on nutritional supplements as scientifically backward and unfortunately, proactive for drug and pharmaceutical interests.

As the institutional safeguard for the foods we eat and the drugs we take, the FDA obviously has a duty to look at these things carefully, and to base its decisions on sound scientific data. We clearly understand the need for this. From where we sit, however, the FDA simply appears to be unable or unwilling to allocate the resources required to do this in the case of nutritional supplements. Under your predecessors, the FDA has even actively engaged in obstructing the dissemination of such information. We would cite the 1992 FDA intervention with the Texas DPH regarding folic acid as a relevant example of such FDA obstruction.

This issue should be squarely addressed on "your watch". Accordingly we urge you to immediately direct approval of labeling criteria which would permit information about the health benefits of saw palmetto, psyllium seed husks, vitamin B6, vitamin B12 and vitamin E. Although far from a complete turn-around, this would be a solid first step in raising the consciousness of Americans about natural food substances and dietary supplements.

Sincerely yours,

Robert & Marilyn Cargill
Concerned Citizens

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99P-3029

C182

CROSS FILE SHEET

File Number: 99P-3029/C182

See File Number: 99P-3030/C181

Robert & Marilyn Cargill
1508 Pine Grove Way
San Jose, CA 95129

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